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Attorneys for Plaintiffs
Par Pharmaceutical, Inc. and
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC. and PAR STERILE PRODUCTS, LLC, Plaintiffs, v. LUITPOLD PHARMACEUTICALS, INC., DAIICHI SANKYO, INC., and DAIICHI SANKYO COMPANY, LTD., Defendants.	C. A. No. ____________ **COMPLAINT FOR PATENT INFRINGEMENT**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Plaintiff Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Plaintiff Par Sterile Products, LLC ("Par Sterile") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Upon information and belief, Defendant Luitpold Pharmaceuticals, Inc. ("Luitpold") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at One Luitpold Drive, Shirley, New York 11967. Upon information and belief, Defendant Daiichi Sankyo, Inc. ("Daiichi Sankyo") is a corporation organized under the laws of the State of Delaware, having a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054. Upon information and belief, Defendant Daiichi Sankyo Company, Ltd. ("Daiichi Sankyo Co.") is a public company organized under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho Chuo-ku, Tokyo, 103-8426, Japan, and having its global clinical development arm, Daiichi Sankyo Pharma Development, at 399 Thornall Street, Edison, New Jersey 08837.

For their Complaint against Luitpold, Daiichi Sankyo, and Daiichi Sankyo Co. (collectively, "Defendants"), Par and Par Sterile (collectively, "Plaintiffs") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,119,876 and 9,295,657 (collectively, the "Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*.

PARTIES

2. Par is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par is a wholly owned, indirect subsidiary of Endo International PLC. Par develops, manufactures and markets pharmaceutical products in the United States. As set forth herein, Par is the assignee of the Patents-in-Suit.

3. Par Sterile is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile is a wholly owned, indirect subsidiary of Endo International PLC. Par Sterile develops, manufactures and markets injectable products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

4. Upon information and belief, Defendant Luitpold is a corporation organized and

existing under the laws of the State of New York, having a principal place of business at One Luitpold Drive, Shirley, New York 11967. Upon information and belief, Luitpold is a wholly owned subsidiary of Daiichi Sankyo Co. Upon information and belief, Luitpold is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Luitpold regularly conducts business in New Jersey. Upon information and belief, Luitpold also provides contract manufacturing services to the biopharmaceutical and pharmaceutical industry.

5. Upon information and belief, Defendant Daiichi Sankyo is a corporation organized under the laws of the State of Delaware, having a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054. Upon information and belief, Daiichi Sankyo is the US division of Daiichi Sankyo Co.

6. Upon information and belief, Defendant Daiichi Sankyo Co. is a public company organized under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho Chuo-ku, Tokyo, 103-8426, Japan, and having its global clinical development arm, Daiichi Sankyo Pharma Development, at 399 Thornall Street, Edison, New Jersey 08837. Upon information and belief, Luitpold's parent company, Daiichi Sankyo Co. regularly conducts business within New Jersey, and has substantial contacts with the State of New Jersey.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Defendants for the reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Luitpold because, *inter alia*, Luitpold has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and

continuous contacts with New Jersey.

10. Luitpold is registered as a pharmaceutical manufacturer in the State of New Jersey under Business ID Number 0400585757.

11. Upon information and belief, Luitpold regularly and continuously transacts business within the state of New Jersey, either on its own or through its affiliates, including selling such pharmaceutical products as DexIron (iron dextran injection, USP) and Venofer (iron sucrose injection). Upon information and belief, Luitpold has agreements with pharmaceutical retailers, wholesalers, or distributors providing for the distribution of its products in the State of New Jersey.

12. Upon information and belief, Luitpold derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

13. In addition, Luitpold has purposely availed itself of this forum by filing suit in at least the following actions: *Luitpold Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, et al., C.A. No. 3-12-05064-JAP (D.N.J.) and *Egalet US, Inc. v. Apotex Corp. et al.*, C.A. No. 1-14-04409-RMB (D.N.J.).

14. Upon information and belief, Luitpold's systematic and continuous business contacts within New Jersey render it at home in New Jersey.

15. This Court has personal jurisdiction over Luitpold insofar as, upon information and belief, it is a wholly owned subsidiary of Daiichi Sankyo, which has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. Daiichi Sankyo has its headquarters at Two Hilton Court, Parsippany, New Jersey 07054.

16. Daiichi Sankyo is the U.S. division of Daiichi Sankyo Co. Daiichi Sankyo Co. has its global clinical development arm, Daiichi Sankyo Pharma Development, at 399 Thornall Street, Edison, New Jersey 08837. Upon information and belief, Daiichi Sankyo Co. directly or indirectly

through Daiichi Sankyo and Luitpold markets, distributes, and sells drug products throughout the United States, including the State of New Jersey.

17. Such significant contacts by Luitpold's parent company, which parent's activities are clearly directed at the forum, further render Luitpold at home in the forum.

18. This Court has personal jurisdiction over Daiichi Sankyo because, *inter alia*, Daiichi Sankyo has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey.

19. Upon information and belief, Daiichi Sankyo is registered in the State of New Jersey under Business ID Number 0100693643 with the business purpose of marketing pharmaceutical products.

20. Upon information and belief, Daiichi Sankyo regularly and continuously transacts business within the State of New Jersey, either on its own or through its affiliates, including marketing pharmaceutical products.

21. Upon information and belief, Daiichi Sankyo derives substantial revenue from its business and marketing activities in the State of New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

22. In addition, Daiichi Sankyo has purposely availed itself of this forum by filing suit in at least the following actions: *Eli Lilly and Company, et al. v. Accord Healthcare, Inc.*, et al., C.A. No. 2-14-01643-CCC (D.N.J.); *Eli Lilly and Company, et al. v. Par Pharmaceuticals Companies, Inc.*, et al., C.A. No. 2-14-00508-CCC (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 2-07-cv-03039-WJM (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Matrix Laboratories, Ltd., et al.*, C.A. No. 2-08-cv-02752-WJM (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 2-06-cv-03462-WJM (D.N.J.).

23. Upon information and belief, Daiichi Sankyo's systematic and continuous business contacts within New Jersey render it at home in the State of New Jersey.

24. This Court has personal jurisdiction over Daiichi Sankyo Co. because, *inter alia*, Daiichi Sankyo Co. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey.

25. Upon information and belief, Daiichi Sankyo Co. regularly and continuously transacts business within the State of New Jersey, either on its own or through its affiliates, including marketing and developing pharmaceutical products. Upon information and belief, Daiichi Sankyo Co.'s global clinical development arm, Daiichi Sankyo Pharma Development, is located at 399 Thornall Street, Edison, New Jersey 08837.

26. Upon information and belief, Daiichi Sankyo Co. derives substantial revenue from its business activities in the State of New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

27. In addition, Daiichi Sankyo Co. has purposely availed itself of this forum by filing suit in at least the following actions: *Eli Lilly and Company, et al. v. Accord Healthcare, Inc.*, et al., C.A. No. 2-14-01643-CCC (D.N.J.); *Eli Lilly and Company, et al. v. Par Pharmaceuticals Companies, Inc.*, et al., C.A. No. 2-14-00508-CCC (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 2-07-cv-03039-WJM (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Matrix Laboratories, Ltd., et al.*, C.A. No. 2-08-cv-02752-WJM (D.N.J.); *Daiichi Sankyo Company, Limited, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 2-06-cv-03462-WJM (D.N.J.).

28. Upon information and belief, Daiichi Sankyo Co.'s systematic and continuous business contacts within New Jersey render it at home in the State of New Jersey.

29. In the alternative, should Daiichi Sankyo Co. contest jurisdiction in this forum, this

Court has personal jurisdiction over Daiichi Sankyo Co. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Daiichi Sankyo Co. is not subject to jurisdiction in any state's courts of general jurisdiction, and because exercising jurisdiction is nevertheless consistent with the United States Constitution given that Daiichi Sankyo Co. has sufficient contacts with the United States.

30. Upon information and belief, this Court has personal jurisdiction over Defendants for the reasons stated herein, including, *inter alia*, Defendants' activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendants at home in the forum.

31. This Court also has personal jurisdiction over Defendants under FEDERAL RULE OF CIVIL PROCEDURE 4(k)(2).

32. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

33. United States Patent No. 9,119,876 ("the '876 patent"), titled "Epinephrine Formulations," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 1, 2015, to Par Pharmaceutical, Inc., the assignee of the named inventors. Par has been, and continues to be, the sole assignee of the '876 patent.

34. A true and correct copy of the '876 patent is attached as Exhibit A.

35. The '876 patent is directed to pharmaceutical compositions comprising epinephrine.

36. United States Patent No. 9,295,657 ("the '657 patent"), titled "Epinephrine Formulations," was duly and legally issued by the PTO on March 29, 2016, to Par Pharmaceutical, Inc., the assignee of the named inventors. Par has been, and continues to be, the sole assignee of the '657 patent.

37. The '657 patent is directed to methods of treating various conditions, such as anaphylaxis and the induction and maintenance of mydriasis during intraocular surgery, by

administering pharmaceutical compositions comprising epinephrine.

38. A true and correct copy of the ’657 patent is attached as Exhibit B.

ADRENALIN®

39. Par Sterile holds approved NDA Nos. 204200 and 204640 for ADRENALIN®, 1 mg base/mL and 30 mg base/30 mL, respectively. ADRENALIN® is the first FDA-approved epinephrine injection product for use in a clinical setting available in the United States. The prescribing information for ADRENALIN® (“ADRENALIN® Label”) instructs physicians to administer ADRENALIN® to patients to treat anaphylaxis and for induction and maintenance of mydriasis during intraocular surgery. Upon information and belief, Defendant Luitpold is currently marketing unapproved forms of epinephrine injection products.

40. Around 2007, FDA announced it would take action against these unapproved drugs due to concerns about the safety, effectiveness, and manufacturing quality of drugs that have not gone through the rigorous FDA-approval process.

41. Despite FDA’s warning, upon information and belief, Defendant Luitpold continues to manufacture or sell its unapproved epinephrine injection products to consumers and patients.

42. ADRENALIN® went through the rigorous FDA-approval process. Plaintiffs’ predecessor, JHP Pharmaceuticals (“JHP”), initially applied for FDA approval of the epinephrine formulation it had marketed for over 100 years. FDA then required JHP to meet strict impurity level requirements for ADRENALIN®. In communications with JHP, FDA expressed that impurities reduced the potency of the product, which could be pharmaceutically unacceptable to patients suffering from emergency anaphylaxis who are in need of potent medication in a short amount of time. JHP undertook a significant initiative to begin developing a new epinephrine formulation that could meet FDA’s impurity requirements.

43. FDA approved NDA No. 204200 (1 mg base/mL) in December 2012 and NDA No.

204640 (30 mg base/30 mL) in December 2013. FDA conditioned its approval on JHP conducting several post-marketing studies and committing to reduce the impurity level of ADRENALIN® further. In particular, because of FDA's concerns and requirements, FDA required JHP to evaluate formulation and process improvements to reduce the levels of impurities, and to take steps to further minimize the level of certain impurities.

44. Par Sterile undertook the post-marketing commitment, and completed the development of a new formulation with significantly fewer impurities as FDA required. Based on the significant research it had conducted, Par Sterile obtained the Patents-in-Suit, which cover the new formulation and methods of using the new formulation to treat various conditions such as anaphylaxis and maintenance of mydriasis during intraocular surgery. In line with its post-marketing commitments that were a condition of approval of NDA Nos. 204200 and 204640, Par Sterile also submitted supplemental NDAs to FDA for approval of the new formulation. In December 2015, FDA approved Par Sterile's supplemental NDA for NDA No. 204640 (30 mg base/30 mL) covering the new formulation. In January 2016, Par Sterile submitted a supplemental NDA for NDA No. 204200 (1 mg base/mL), which supplement is currently under review. Upon information and belief, FDA will shortly approve the new formulation supplement for NDA No. 204200 (1 mg base/1 mL epinephrine), which belief is reasonable since FDA has already approved the corresponding new formulation supplement for Par Sterile's NDA No. 204640 (30 mg base/30 mL epinephrine).

45. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '876 and '657 patents were listed in the Orange Book with respect to ADRENALIN®.

DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

46. Upon information and belief, Luitpold submitted ANDA No. 207-568 to FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of ADRENALIN® (epinephrine injection), prior to the expiration of the Patents-in-Suit.

47. By a letter dated March 9, 2016 (the "Notice Letter"), Luitpold stated that it had submitted ANDA No. 207-568 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of ADRENALIN® (epinephrine injection) prior to the expiration of the Patents-in-Suit.

48. Upon information and belief, Defendants' reference listed drug ("RLD") is ADRENALIN®, which means that Defendants' generic version of ADRENALIN® (epinephrine injection) will be the pharmaceutical equivalent of ADRENALIN®. Upon information and belief, Defendants are relying on and incorporating by reference the safety and efficacy information that FDA relied upon in making its final determination of approval for ADRENALIN®.

49. The Notice Letter also stated that ANDA No. 207-568 contains a "Paragraph IV" certification that alleges the '876 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Defendants' generic version of ADRENALIN® (epinephrine injection). The Notice Letter did not include any arguments that the Patents-in-Suit are invalid or unenforceable.

50. In the Hatch-Waxman context, the infringement analysis is dictated by the contents of Defendants' ANDA and ongoing ANDA supplements and/or amendments, as well as FDA's likely requirements for the drug composition and formulation that will be finally approved. The infringement analysis is not dictated by the contents of any of Defendants' manufacturing guidelines, existing products, or Defendants' "guarantees" of what FDA will approve. *See Sunovion Pharm.*,

Inc. v. Teva Pharm. USA, Inc., 731 F.3d 1271, 1279 (Fed. Cir. 2013). The scope of what Defendants "ask[] for and receive[] approval to market, if within the scope of a valid claim, is an infringement." *Id.*

51. Because Defendants' ANDA has not yet been approved, the infringement inquiry necessarily focuses on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Bayer AG v. Elan Pharmaceutical Res. Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)). Here, the infringement inquiry necessarily focuses on the product that Defendant Luitpold will likely market if its ANDA receives final FDA approval ("Luitpold's Generic Product").

52. Upon information and belief, and after a reasonable opportunity for further investigation and discovery, Defendants have represented to FDA that Luitpold's Generic Product will have the same active ingredient as ADRENALIN®, the same or equivalent inactive ingredients as ADRENALIN®, and the same route of administration as ADRENALIN®. Upon information and belief, and after a reasonable opportunity for further investigation and discovery, Defendants have represented to FDA that Luitpold's Generic Product will be bioequivalent to ADRENALIN®. Upon information and belief, and after a reasonable opportunity for further investigation and discovery, Defendants have represented to FDA that Luitpold's Generic Product will have the same indication as ADRENALIN®.

53. FDA conditioned approval of ADRENALIN® on its formulation having low levels of impurities, and upon JHP's commitment to perform post-marketing studies and reduce the impurity levels further. Upon information and belief, and upon a reasonable opportunity for further investigation and discovery, Luitpold proposed a product to FDA having impurity levels higher than the levels in ADRENALIN®. Upon information and belief, just as it did while evaluating ADRENALIN®, FDA will require Luitpold's Generic Product to have reduced impurity levels.

Upon information and belief, FDA will require Luitpold's Generic Product to have the same or equivalent ingredients and, therefore, the same or equivalent formulation as ADRENALIN®, to, *inter alia*, reduce the impurity levels.

54. Upon information and belief, Luitpold's Generic Product will have a formulation covered by one or more claims of the '876 patent and will be administered to practice the methods covered by one or more claims of the '657 patent.

55. On information and belief, and after a reasonable opportunity for further investigation and discovery, Luitpold's ANDA essentially copies the ADRENALIN® Label as required by FDA under 21 C.F.R. § 314.94(a)(iv), and therefore the label for Luitpold's Generic Product will instruct physicians to administer Luitpold's Generic Product (epinephrine injection) to treat anaphylaxis and for induction and maintenance of mydriasis during intraocular surgery. On information and belief, physicians will follow these instructions in the label for Luitpold's Generic Product. The use of Luitpold's Generic Product to treat these conditions is an infringement of the claims of the '657 patent. By seeking approval of a label that instructs physicians to practice the patented methods, Defendants are actively inducing infringing acts with a specific intent to encourage infringement of the '657 patent.

56. Defendants have known of the '657 patent at least as early as the filing of this Complaint. Defendants have known of the '876 patent at least as early as March 9, 2016, the date of the Notice Letter.

57. Upon information and belief, Defendants will also contributorily infringe one or more claims of the '657 patent under 35 U.S.C. § 271(c) in that Defendants will make, use, sell, offer to sell, and/or import Luitpold's Generic Product, which Defendants know have no substantial non-infringing uses. Luitpold's Generic Product will be a material part of practicing the methods of treating anaphylaxis and for the induction and maintenance of mydriasis during intraocular surgery

claimed in the ’657 patent because Luitpold’s Generic Product will be a pharmaceutical equivalent to ADRENALIN®, and ADRENALIN® is indicated to treat those two conditions.

58. On information and belief, the manufacture, importation, use, offer for sale, or sale of Luitpold’s Generic Product will occur at Defendants’ behest, and with their intent, knowledge and encouragement.

59. Upon information and belief, Defendants Daiichi Sankyo and Daiichi Sankyo Co. participated in, contributed to, actively induced, encouraged, aided, or abetted Luitpold’s preparation, submission, and filing of ANDA No. 207-568 with a paragraph IV certification.

60. Defendants Daiichi Sankyo and Daiichi Sankyo Co.’s inducement, encouragement, aiding, or abetting of Luitpold’s preparation, submission, and filing of ANDA No. 207-568 with a paragraph IV certification constitutes infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A). Further, Defendants Daiichi Sankyo and Daiichi Sankyo Co.’s manufacture, commercial use, sale, offer for sale, and/or importation of Luitpold’s Generic Product would induce and/or contribute to Luitpold’s infringement of the Patents-in-Suit under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

61. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I
(Infringement of the ’876 Patent by Defendants)

62. Plaintiffs incorporate each of the preceding paragraphs 1 to 61 as if fully set forth herein.

63. Defendant Luitpold’s submission of ANDA No. 207-568, including its inclusion of section 355(b)(2)(A)(iv) allegations, constitutes infringement of the ’876 patent pursuant to 35 U.S.C. § 271(e)(2).

64. On information and belief, upon FDA approval of NDA No. 207-568, Defendants will infringe the ’876 patent by making, using, offering to sell, or selling Luitpold’s Generic Product in the United States and/or importing Luitpold’s Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

65. Defendants Daiichi Sankyo and Daiichi Sankyo Co.’s inducement, encouragement, aiding, or abetting of Luitpold’s preparation, submission, and filing of ANDA No. 207-568 with a paragraph IV certification constitutes infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A). Further, Defendants Daiichi Sankyo and Daiichi Sankyo Co.’s actions in encouraging, promoting, contributing to, aiding and/or abetting the manufacture, commercial use, sale, offer for sale, and/or importation of Luitpold’s Generic Product would infringe or induce and/or contribute to Luitpold’s infringement of the ’876 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

COUNT II
(Declaratory Judgment of Infringement of the ’876 Patent by Defendants)

66. Plaintiffs incorporate each of the preceding paragraphs 1 to 65 as if fully set forth herein.

67. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Luitpold’s Generic Product within the United States, import Luitpold’s Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the ’876 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

69. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III
(Infringement of the '657 Patent by Defendants)

70. Plaintiffs incorporate each of the preceding paragraphs 1 to 69 as if fully set forth herein.

71. Defendant Luitpold's submission of ANDA No. 207-568 constitutes infringement of the '657 patent pursuant to 35 U.S.C. § 271(e)(2).

72. Upon FDA approval of ANDA No. 207-568, Defendants will infringe the '657 patent by making, using, offering to sell, or selling Luitpold's Generic Product in the United States and/or importing Luitpold's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

73. Defendants Daiichi Sankyo and Daiichi Sankyo Co.'s inducement, encouragement, aiding, or abetting of Luitpold's preparation, submission, and filing of ANDA No. 207-568 with a paragraph IV certification constitutes infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A). Further, Defendants Daiichi Sankyo and Daiichi Sankyo Co.'s actions in encouraging, promoting, contributing to, aiding and/or abetting the manufacture, commercial use, sale, offer for sale, and/or importation of Luitpold's Generic Product would induce and/or contribute to Luitpold's infringement of the '657 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

COUNT IV
(Declaratory Judgment of Infringement of the '657 Patent by Defendants)

74. Plaintiffs incorporate each of the preceding paragraphs 1 to 73 as if fully set forth herein.

75. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Luitpold's Generic Product within the United

States, import Luitpold's Generic Product into the United States, or induce or contribute to such conduct, Defendants will infringe the '657 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g), literally and/or through the doctrine of equivalents.

77. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants infringed, contributed to, or induced the infringement of each of the claims of the Patents-in-Suit, literally and/or through the Doctrine of Equivalents by contributing to, inducing the submission of, or submitting ANDA No. 207-568;

B. A declaration that if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Luitpold's Generic Product within the United States, import Luitpold's Generic Product into the United States, or induce or contribute to such conduct, Defendants infringe the Patents-in-Suit pursuant to 35 U.S.C. § 271(a), (b), or (c);

C. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of ANDA No. 207-568 shall not be earlier than the expiration dates of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An order requiring Luitpold to amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

E. A preliminary and permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of Luitpold's Generic Product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or may become entitled;

F. That Plaintiffs be awarded monetary relief if Defendants commercially manufacture, use, offer for sale, or sell Luitpold's Generic Product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the United States before the latest expiration date of any of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

G. An award of costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: April 22, 2016

The Law Office Of
JASON B. LATTIMORE, ESQ. LLC

s/ Jason B. Lattimore
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that infringement of the Patents-in-Suit in the above-captioned action is also the subject of the action *Par Pharmaceutical, Inc., et al. v. Luitpold Pharmaceuticals, Inc.*, filed simultaneously in the Eastern District of New York. The case number has not yet been assigned.

I hereby certify that infringement of the Patents-in-Suit in the above-captioned action, to the best of my knowledge, is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: April 22, 2016

THE LAW OFFICE OF
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